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10/624,443	07/22/2003	Thomas G. Rehberger	362.017	6437

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



### **DETAILED ACTION**

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group II, claims 19-35 on 4/26/06 is acknowledged.

Claims 19-35 are being considered on the merits. Claims 1-18 and 36-39 are withdrawn from consideration as directed to a non-elected invention.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-22, 25, 27-29 are rejected under 35 U.S.C. 101 because this claim reads on the organism per se which is found in nature and thus, is unpatentable to applicant. Consequently, the claim does not embody patentable subject matter as defined in 35 USC 101. See, e.g., *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931); *Funk Brothers Seed. Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948); *Diamond v. Chakrabarty*, 206 U.S.P.Q. 193 (1980).

It is suggested that applicant use the language "a biologically pure culture" in connection with the strain to identify a product that is not found in nature and to indicate the hand of man.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 19 is vague, indefinite and confusing in the recitation of “that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6. The genus of *Lactobacillus* strains intended to be encompassed by this terminology cannot be readily assessed. There is no clear indication as to how many Profile I there are and whether there are other means of obtaining or reaching this designation. In addition, the Figure is not clearly legible. Thus, the results depicted therein cannot be interpreted or ascertained. Table 6 provides strain designations and species designations, but the correlation with Profile I is unclear. The Figure and Table are not informative regarding the specific properties of the strains intended to be claimed. The reasons or criteria for designating pigs as “representative” for inclusion in Table 6 data are not set forth with any particularity on the record..

Claim 26 is vague and indefinite in the recitation of a “milk replacer”, since the nature of the material intended is unclear. Milk can be replaced by water or any other liquid.

Claims 23 and 34 respectively 24 and 35 appear to be substantial duplicates.

Claims 24 and 35 are confusing in that it is unclear how many pars aesophagae a pig has as suggested by “a pars aesophagae.”

Claims 21-22 and 31 are vague and indefinite in the recitation “wherein the strain comprises ... strain ”. It does not appear that a strain may comprise a strain. Replacement of “comprises” with --is-- would be remedial.

Claims 20 and 32 are vague and indefinite in the recitation of “at least one of coliforms and *E. coli*”, since *E. coli* is a coliform.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The invention appears to employ a specific strain of *L. brevis*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It does not appear that a deposit was made in this application as filed that meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

#### SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

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Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-28, 30-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tannock *et al.*.

The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 which has been optionally isolated from a pig.

Tannock *et al.* discloses at least one *Lactobacillus* strain that has a Profile I which has been optionally isolated from a pig. See, e.g., page 1313. The strains are identified as *L. fermentum*.

Claims 19-28, 30-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Krause *et al.*, (Anaerobe (1997), 3(5), 317-325).

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The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 which has been optionally isolated from a pig.

The cited reference discloses at least one *Lactobacillus* strain that which appears to be identical to the presently claimed strain (see, e.g., Table I, page 320) since it is presumed to have Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 because it has been isolated from the gastrointestinal tract of a pig. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since it is of the same class as that of the microorganism claimed., including the same species.. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 19-28, 30-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Benoit *et al.*, (Current Microbiology Volume 28, Number 1 Date: January 1994 Pages: 53 - 61).

The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 which has been optionally isolated from a pig.

The cited reference discloses at least one *Lactobacillus* strain that which appears to be identical to the presently claimed strain (see, e.g., Table I, page 54) since it is presumed to have Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 because it has been isolated from pig. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since it is of the same

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class as that of the microorganism claimed., including the same species.. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 19-28, 30-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Coventry et al., (J. Appl. Bacteriol, 1996 Jan;80(1):91-8.) The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 which has been optionally isolated from a pig.

The cited reference discloses at least one *Lactobacillus* strain that which appears to be identical to the presently claimed strain (see, e.g., col. 1, page 91) since it is presumed to have Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 because it has been isolated from pig. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since it is of the same class as that of the microorganism claimed., including the same species.. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.



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Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 19-28, 30-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schutz, *et al.*, (System. Appl. Microbiol., 5:169 (1984)). The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 which has been optionally isolated from a pig.

The cited reference discloses at least one *Lactobacillus* strain that which appears to be identical to the presently claimed strain (see, e.g., page 170) since it is presumed to have Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 because it belongs to the same species as included in the claimed invention and is considered to anticipate the claimed microorganism. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 19-28, 30-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewus, et al. Detection of bacteriocins produced by lactic acid bacteria, Journal of Microbiological Methods 13(2) 145-150. 1991.

The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 which has been optionally isolated from a pig.

The cited reference discloses at least one *Lactobacillus* strain that which appears to be identical to the presently claimed strain (see, e.g., Table 1, page 147) since it is presumed to have Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 because it

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belongs to the same species as included in the claimed invention and is considered to anticipate the claimed microorganism. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary. Claims 19-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tannock *et al.* taken with Krause *et al.*, Craig *et al.* (U.S. Patent No. 5,795,602) and Iritani *et al.* (U.S. Patent No. 6,090,416)

The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I and Table 6 which has been optionally isolated from a pig.

Each of Tannock *et al.* and Krause *et al.* discloses at least one *Lactobacillus* strain that has a Profile I which has been isolated from the gastrointestinal tract of a pig. See, e.g., page 1313 and 320, respectively. The strains are identified as *L. fermentum* or *L. brevis*. At least the strains of Tannock *et al.* are shown to possess a Profile I. It is noted that agar is a gel paste at least to some extent.

The references may differ from the claimed invention in that a gruel feed is not taught as a carrier for at least one *Lactobacillus* strain.. However, Iritani *et al.* adequately demonstrate that fermented compositions are provided in the form of gruel, which material also may act as a milk replacer upon dilution. See, e.g., Examples. In addition, Craig *et al.* disclose the benefits of probiotics added to milk, which one of ordinary skill in the art would have recognized to be similarly beneficial when added to milk replacers or to other food materials. See, e.g., col. 2, lines 50-60 and col. 5, lines 15-27.

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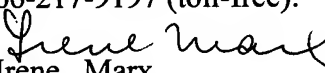
It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the products of Tannock *et al.* and Krause *et al.* by providing the probiotics disclosed by the references in conjunction with a gruel composition or a diluted gruel composition as suggested by the teachings of Iritani *et al.* and Craig *et al.* for the expected benefit of providing required nutrients in combination with probiotics known to favorably affect the gastrointestinal flora by displacing deleterious microorganisms at least by competitive exclusion.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Irene Marx  
Primary Examiner  
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